Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Proposed Re-evaluation Decision PRVD2010-08

Sodium Fluoride

(publié aussi en français)

4 May 2010

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

HC Pub: 100167

ISBN: 978-1-100-15562-3 (978-1-100-15563-0)
Catalogue number: H113-27/2010-8E (H113-27/2010-8E-PDF)

Table of Contents

Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the antimicrobial sodium fluoride, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing sodium fluoride in Canada.

An evaluation of available scientific information found that products containing sodium fluoride do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of sodium fluoride uses, new risk-reduction measures must be included on the labels of all products. Additional data are being requested as a result of this re-evaluation.

It should be noted that for end-use products containing more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

This proposal affects all end-use products containing sodium fluoride registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for sodium fluoride and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of sodium fluoride.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

---

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health *and* the environment. Regulatory Directive DIR2001-03, PMRA *Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Sodium fluoride, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy).

Based on their health and environmental risk assessments published in 2007, the USEPA concluded that sodium fluoride was eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in their risk assessments were an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Is Sodium Fluoride?

Sodium fluoride is an antimicrobial that is used as a remedial wood preservative on industrial posts, poles, timbers and crossties. Sodium fluoride is formulated as a paste, an impregnated fabric, or a solid cartridge. It is applied by professional applicators using a grease gun or pressurized applicator for interior pole treatments, or using a brush or fabric wrapping for exterior pole treatments.

Health Considerations

Can Approved Uses of Sodium Fluoride Affect Human Health?

Sodium fluoride is unlikely to affect your health when used according to the revised label directions.

People could be exposed to sodium fluoride by working as a handler or by contacting treated wood. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that sodium fluoride was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Environmental Considerations

What Happens When Sodium Fluoride Is Introduced Into the Environment?

Sodium fluoride is unlikely to affect non-target organisms when used according to the revised label directions.

The USEPA concluded that the reregistration of sodium fluoride was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of sodium fluoride, the PMRA is proposing further risk-reduction measures for product labels.

- Certification of handlers.
- Additional protective equipment for handlers.
- Requirement for the use of brushes with elongated handles for paste applications.
- Additional advisory label statements prohibiting use on children's playground equipment, picnic tables, or other products with food/feed contact surface areas.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix I lists all data requirements.

Next Steps

Before making a final re-evaluation decision on sodium fluoride, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

---

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Sodium fluoride is an antimicrobial pesticide, which is used as a remedial wood preservative. It acts by inhibiting enzyme activity and calcium metabolism by binding to metal-containing enzymes and calcium.

Following the re-evaluation announcement for sodium fluoride, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the labels of commercial class end-use products in Canada.

The PMRA used recent assessments of sodium fluoride from the USEPA. The USEPA RED document for sodium fluoride, dated 2007, as well as other information on the regulatory status of sodium fluoride in the United States can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	sodium fluoride
Function	antimicrobial, wood preservative
Chemical Family	fluoride salt
Chemical name	sodium fluoride
1 International Union of Pure and Applied Chemistry (IUPAC)	sodium fluoride
2 Chemical Abstracts Service (CAS)	sodium fluoride
CAS Registry Number	7681-49-4
Molecular Formula	NaF
Structural Formula	NaF
Molecular Weight	42.0 atomic mass units
Purity of the Technical Grade Active Ingredient	97.5% (nominal)
Registration Number	25705

Based on the manufacturing process used, contaminants of human health or environmental concern as identified in the Canada Gazette, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25), including Toxic Substances Management Policy Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	$\leq 1 \times 10^{-6}$ mm Hg
Henry's law constant	$< 10^{-6}$ atm·m^3·mole^{-1}
Ultraviolet–visible spectrum	No ultraviolet absorbing chromophore
Solubility in water	> 100 ppm
***n*-Octanol–water partition coefficient (K_{ow})**	Log $K_{ow} < 3$

2.3 Comparison of Use Patterns in Canada and the United States

Sodium fluoride is an antimicrobial registered in Canada to prevent wood decay. It is used as a remedial wood preservative on industrial posts, poles, timbers and crossties. The end-use products are formulated as a solid cartridge, a paste or an impregnated fabric. Sodium fluoride is applied to the wood interior by inserting solid cartridges (92.6% a.i. guarantee) or paste (44.4% a.i. guarantee) into drilled holes. Sodium fluoride is also applied to the wood exterior by brushing on paste or by wrapping impregnated fabric (70.6% a.i. guarantee) around the pole. All treatments using sodium fluoride are sealed after application.

The American and Canadian use patterns were compared. The Canadian formulation types of end-use products and the use of sodium fluoride as a remedial wood preservative are among those registered in the United States. Based on this comparison of use patterns, it was concluded that the USEPA RED for sodium fluoride is an adequate basis for the re-evaluation of uses of sodium fluoride in Canada.

All current uses are being supported by the registrants and were, therefore, considered in the re-evaluation of sodium fluoride. Appendix II lists all sodium fluoride products that are registered as of 1 November 2009, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 2007 RED, the USEPA concluded that the end-use products formulated with sodium fluoride met the safety standard under the American *Federal Insecticide, Fungicide and Rodenticide Act* and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the amended product labels.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

In Canada, exposure to sodium fluoride may occur while working as a handler or by contacting treated wood. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target margin of exposure incorporating safety factors protective of the most sensitive subpopulation. If the calculated margin of exposure is less than the target margin of exposure, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

The USEPA's toxicological endpoints for assessing risk from occupational exposure are summarized in Appendix III.

Workers can be exposed to sodium fluoride through handling the pesticide and when contacting treated wood to conduct handling or maintenance activities of poles, posts and crossties.

3.1.1.1 Handler Exposure and Risk

Three dermal and inhalation exposure scenarios for handlers were identified and assessed by the USEPA:

- Interior treatment of poles (solid cartridges)
- Interior treatment of poles (liquid spray)
- Exterior treatment of poles (paste brush-on)

Handler exposure analyses were conducted using surrogate exposure data from the Pesticide Handlers Exposure Database (PHED), assuming personal protective equipment consisting of long pants, a long-sleeved shirt and chemical-resistant gloves. Dermal and inhalation risks were assessed using:

- maximum application rates of 0.21 kg a.i./pole and 0.89 kg a.i./pole for interior and exterior applications, respectively,
- a target MOE of 300 for short-term and long-term durations, and a target MOE of 100 for intermediate-term durations, based on no observed adverse effect levels of 20, 1.5 and 1.3 mg/kg bw/day for short-, intermediate-, and long-term durations, respectively.

1) Interior treatment of poles (solid cartridges)
The USEPA considered sodium fluoride solid cartridges to be injected into pre-drilled holes and capped via closed and automated systems; therefore, inhalation and dermal exposures were expected to be minimal. It was concluded that in the event of a spill, potential exposure and risk would be mitigated via the personal protective equipment already required on the label (chemical-resistant gloves, goggles, long pants, and long sleeved-shirt). The same personal protective equipment are currently required on the Canadian label.

2) Interior treatment of poles (liquid spray)
For the interior treatment of poles, the USEPA considered liquid spray injection to be a "worst-case scenario" encompassing the paste application. Acceptable short-, intermediate- and long-term inhalation MOEs ranging from 2900 to 56 000 were reported. Dermal MOEs of concern, ranging from 18 to 280, were reported for all durations.

3) Exterior treatment of poles (paste brush-on)
For the exterior treatment of poles, the USEPA considered that the brush-on scenario using paste encompasses the application using impregnated fabric. The inhalation exposure was expected to be minimal based on the vapour pressure and viscosity of the paste formulation. Dermal MOEs of concern of less than or equal to 2 were reported for all durations. This assessment was considered to be conservative based on a default dermal absorption factor of 100% and the fact that significant dermal absorption is not expected based on the chemical properties of sodium fluoride.

The RED is considered to adequately address the potential exposure scenarios associated with the Canadian use as a wood preservative of products containing sodium fluoride, i.e., interior treatment of poles using solid cartridges or paste and exterior treatment of poles using paste or impregnated fabric. Therefore, the conclusions derived from the RED for these scenarios are considered applicable to the Canadian situation. Based on the RED, the following mitigation measures are proposed to further protect workers:

- Long pants, long-sleeved shirt, chemical-resistant gloves plus chemical-resistant sleeves, a chemical-resistant apron and a face shield or goggles during handling of all products.
- Brushes with elongated handles (at least one metre in length) for brush-on applications.
- Additional label statements to ensure that sodium fluoride end-use products are handled by trained workers.

The proposed label amendments are listed in Appendix IV.

Additionally, the PMRA requires data to refine the dermal risk assessment of the paste applications. A 90-day dermal study with the technical grade active ingredient and an occupational exposure study with a relevant formulation are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. See Section 7.0 for the specific data requirements.

3.1.1.2 Postapplication Exposure and Risk

Considering that treated holes are capped and groundline treatments are covered after application, as well as the low vapour pressure of sodium fluoride, the USEPA concluded that the potential for dermal exposure from postapplication activities of workers would be minimal. No additional risk mitigation measures were required.

The USEPA conclusions are considered applicable to the Canadian situation, and no mitigation measures are required to further protect workers from postapplication exposure.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

Based on the registered uses, the USEPA expected negligible residential exposure to sodium fluoride. Although treated utility poles are numerous and often located in people's front yards, they concluded that, considering the use pattern and low vapour pressure, potential exposure to children playing in areas of treated poles would be minimal. Therefore, no additional mitigation measures were required.

The conclusions derived from the RED are considered applicable to the Canadian situation. The PMRA is proposing that all end-use product labels include a statement indicating that the product is not to be used for children's playground equipment or picnic tables. The proposed label amendments are listed in Appendix IV.

3.1.2.2 Exposure From Food and Drinking Water

Dietary (food) exposure to sodium fluoride was not expected, and the USEPA also determined that the antimicrobial uses of sodium fluoride were not expected to have an impact on either surface or groundwater resources. On this basis, it was concluded that acute and chronic dietary (food and drinking water) risk assessments were not required.

The conclusions derived from the RED are considered applicable to the Canadian situation. The PMRA is proposing that all end-use product labels include a statement indicating that the product is not to be used to treat food/feed contact surface areas. In addition, based on the use pattern as a wood preservative and the results from the USEPA sodium fluoride water monitoring study, environmental exposure is expected to be minimal (see Section 3.2.1). Therefore, no further mitigation measures are required at this time.

3.1.2.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to sodium fluoride (food, water and residential exposures). The USEPA did not perform an aggregate exposure assessment since there were no dietary, residential or other non-occupational sources of exposure to sodium fluoride.

The conclusions derived from the RED are considered applicable to the Canadian situation.

3.1.3 Cumulative Effects

The USEPA has not determined whether sodium fluoride has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that sodium fluoride does not share a common mechanism of toxicity with other substances, and a cumulative risk assessment was not required.

3.2 Environment

3.2.1 Environmental Risk Assessment

The USEPA determined that sodium fluoride is not bioaccumulative (Log K_{ow} of -0.77), and is not expected to adversely affect soil biomass, soil microflora or soil macroinvertebrates. In addition, based on a soil monitoring study around sodium fluoride treated poles, it was determined that contamination of groundwater or surface water was not expected.

Sodium fluoride was not likely to result in unacceptable acute or chronic risk to non-target organisms considering that sodium fluoride has a minimal exposure potential based on the use pattern and a low to slightly low toxicity to non-target species. Overall, the USEPA required additional label statements to further protect the environment from sodium fluoride discharge.

Conclusions derived from the RED are considered relevant to the Canadian situation. Proposed label amendments are listed in Appendix IV.

3.3 Pest Control Product Policy Considerations

3.3.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy, in other words, CEPA-toxic or equivalent, predominantly anthropogenic, persistent and bio-accumulative).

During the Re-evaluation process, sodium fluoride was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy,* and evaluated against the Track 1 criteria for persistence and bioaccumulation. In order for sodium fluoride or its transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met. The PMRA has reached the following conclusion:

- Sodium fluoride does not meet Track 1 criteria, and is not considered a Track 1 substance. The table below shows a comparison of sodium fluoride's fate characteristics with Track 1 criteria.

Table 1. Toxic Substances Management Policy Considerations – Comparison to Toxic Substances Management Policy Track 1 Criteria

Toxic Substances Management Policy Track 1 Criteria	Toxic Substances Management Policy Track 1 Criterion Value		Sodium Fluoride's Fate Characteristic Value	Criterion Met
Persistence	Air	Half-life ≥ 2 days or evidence of long range transport	Volatilisation is not an important route of dissipation and long-range transport is unlikely based on the vapour pressure (5.43×10^{-26} mm Hg at 25°C) and Henry's Law Constant (5.04×10^{-33} atm · m^3·$mole^{-1}$).	no
Bioaccumulation	Log *n*-octanol–water partition coefficient ≥ 5		-0.77	no

3.3.2 Contaminants and Formulants of Health or Environmental Concern

During the Re-evaluation of sodium fluoride, contaminants in the technical grade active ingredient are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

- Technical grade sodium fluoride does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

4.0 Incident reports

Starting 26 April 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame.

There were no incident reports submitted for sodium fluoride as of 1 November 2009.

5.0 Organisation for Economic Co-operation and Development Status of Sodium Fluoride

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 30 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

Based on the available information, sodium fluoride is not registered for use in biocidal products in the European Union.

As described earlier in this document, the United States, also an OECD member, assessed the registration of all uses of sodium fluoride in 2007 and concluded that using sodium fluoride as a pesticide does not result in unreasonable adverse effects to human health or the environment provided the risk-reduction measures recommended in the RED document were implemented.

The Canadian re-evaluation of sodium fluoride is largely based on the 2007 USEPA assessments. As described in Sections 3.1 and 3.2, the PMRA has found the USEPA human health and environmental risk conclusions to be relevant to the use of sodium fluoride in Canada and requires measures to further protect workers and the environment.

6.0 Proposed Re-evaluation Decision

The PMRA has determined that sodium fluoride is acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment. The labels of Canadian end-use product must be amended to include the label statements listed in Appendix IV. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. The registrant of the technical grade active ingredient is required to submit data as a condition of continued registration under Section 12 of the *Pest Control Products Act*. Appendix I lists data requirements.

It should be noted that for end-use products containing more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

7.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and data code tables can be found on the Pesticides and Pest Management portion of Health Canada's website at www.healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal Toxic Substances Management Policy is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for sodium fluoride is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

The European Union Directive 98/8/EC on biocidial products is available on the European Commission's webpage at http://ec.europa.eu/environment/biocides/index.htm.

Canada Gazette, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette,* Part II, Volume 142, Number 13, pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

List of Abbreviations

a.i.	active ingredient
atm	atmosphere
bw	body weight
CAS	Chemical Abstracts Service
DACO	data code
FQPA	*Food Quality Protection Act*
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
LOAEL	lowest observed adverse effect level
m^3	metre cubed
mg	milligram(s)
mm Hg	millimetre mercury
MOE	margin of exposure
NaF	sodium fluoride
NOAEL	no observed adverse effect level
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
PCPA	*Pest Control Products Act*
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

Appendix I Additional Data Requirements

The following data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of sodium fluoride are required to provide these data or an acceptable scientific rationale within the timeline specified in the decision letter that will be sent to registrants of the technical grade active ingredients by the PMRA.

- DACO 4.3.4 Short-term Dermal (90-day) Study

  This study must be conducted with the Canadian technical grade active ingredient or a product with equivalent formulation and guarantee and be conducted according to the appropriate USEPA Office of Prevention, Pesticides and Toxic Substances or Organisation for Economic Co-operation and Development guidelines.

- DACO 5.4 Mixer/Loader/Applicator: Passive Dosimetry Data.

  This study must be conducted with a relevant end-use product and be conducted according to the appropriate USEPA Office of Prevention, Pesticides and Toxic Substances or Organisation for Economic Co-operation and Development guidelines.

Appendix II Registered Products Containing Sodium Fluoride as of 1 November 2009

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
25705	Technical	Timber Specialties Co.	Sodium Fluoride Powdered	soluble powder	97.5
25708	Commercial	North Star Structural Contractors Limited	COP-R-Plastic Wood Preserving Compound	paste	44.4
25709	Commercial	North Star Structural Contractors Limited	Flurods	solid	92.6
25711	Commercial	North Star Structural Contractors Limited	Pole Wrap	impregnated fabric	70.6

Appendix III Toxicological Endpoints for Sodium Fluoride Health Risk Assessments

Exposure Scenario	Dose (mg/kg bw/day)	Study	Target MOE[a] (FQPA Safety Factor)
Acute dietary (general population and females 13–49) and Chronic Dietary	No appropriate endpoints were identified that represent a single dose effect. Therefore, this risk assessment is not required.		
Short-term dermal (1–30 days)	Oral LOAEL = 20	Oral subchronic toxicity study in rats	300
Intermediate-term dermal (30 days–6 months)	Oral NOAEL = 1.5	6-month NTP oral toxicity study in mice	100
Long-term dermal (> 6 months)	LOAEL = 1.3	2-year NTP chronic toxicity/ carcinogenicity study in rats	300
Short-term inhalation (1–30 days)	Oral LOAEL = 20	Oral subchronic toxicity study in rats	300
Intermediate-term inhalation (30 days–6 months)	Oral NOAEL = 1.5	6-month NTP oral toxicity study in mice	100
Long-term inhalation (> 6 months)	LOAEL = 1.3	2-year NTP chronic toxicity/ carcinogenicity study in rats	300
Cancer	Sodium fluoride has been classified as a "Group D" (not classifiable as to carcinogenicity). This conclusion was considered with the recent report by the National Academy of Sciences which concluded that 'the evidence on the potential of fluoride to initiate or promote cancers, particularly of the bone, is tentative and mixed.'		

[a] Desired margin of exposure (MOE) for occupational assessments; the target MOE of 300 is based on 10× interspecies extrapolation, 10× intraspecies variation and 3× for the use of a lowest observable adverse effect level; the target margin of exposure of 100 is based on 10× interspecies extrapolation and 10× intraspecies variation.

NTP = National Toxicology Program; FQPA = *Food Quality Protection Act*; NOAEL = no observed adverse effects level; LOAEL = lowest observed adverse effects level.

Appendix IV Label Amendments for Products Containing Sodium Fluoride

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) Add to the **PRIMARY PANEL**:

This product is only to be used by individuals holding an appropriate pesticide applicator certificate or license recognized by the provincial/territorial pesticide regulatory agency where the pesticide application is to occur.

II) Add to **PRECAUTIONS**:

Wear long pants, a long-sleeved shirt, chemical-resistant gloves plus chemical-resistant sleeves, a chemical-resistant apron, and a face shield or goggles during handling.

III) Add to **DIRECTIONS FOR USE**:

Equipment for the brush-on applications is limited to only brushes that have handles that are at least one (1) metre in length.

DO NOT use this product to treat children's playground equipment, picnic tables or other products with food/feed contact surface areas.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

References

Studies considered in the Chemistry Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA Document Number	Reference
1254154	1995. Chemistry: Flurods, Sodium Fluoride. 13 November 1995 (Pages#122-124). (SUBN #95-1783), DACO: 3 CBI
1254989	1997. Chemistry: Analysis of Production Batch Samples of Pole Wrap. September 15, 1997. (33-59; 1942-96; 199-43-X). SUBN #95-0693., DACO: 3 CBI
1766810	1996. SFL-CIU-1 Amendment of Product Chemistry – Chemistry Analysis, Physical Properties, Containers, Freight Description., DACO: 2.0, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.9, 2.14.4, 2.14.5, 2.14.6, 2.14.7 CBI
1766822	1995. SFL-CIU-1 Response to Letter of August 10, 1995 – Sodium Fluoride Sampling Schematic, and Label. Product Chemistry Data. Sax's Dangerous Properties of Industrial materials – Eighth Edition Volume II., DACO: 2.0 CBI
1766832	1995. SFL-CIU-1 Product Chemistry and Attachments A, B, C. Preliminary Analysis, Analytical Method, Product Chemistry Study., DACO: 2.1, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.99 CBI